DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Medis medical imaging systems, b.v.
% Bob Goedhart, Ph.D.
VP Corporate R&D
Schuttersveld 9
2316 XG Leiden
THE NETHERLANDS

January 6, 2015

Re: K140587
Trade/Device Name: MR-CT VVA
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 7, 2014
Received: November 10, 2014

Dear Dr. Goedhart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140587

Device Name
MR-CT VVA

Indications for Use *(Describe)*
MR-CT VVA is indicated for use in clinical settings where more reproducible than manually derived quantified results are needed to support the visualization and analysis of MR and CT images of the heart and blood vessels for use on individual patients with cardiovascular disease. Further, MR-CT VVA allows the quantification of T2* in MR images of the heart and the liver. Finally, MR-CT VVA can be used for the quantification of cerebral spinal fluid in MR velocity-encoded flow images.

When the quantified results provided by MR-CT VVA are used in a clinical setting on MR and CT images of an individual patient, they can be used to support the clinical decision making for the diagnosis of the patient. In this case, the results are explicitly not to be regarded as the sole, irrefutable basis for clinical diagnosis, and they are only intended for use by the responsible clinicians.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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5. 510(k) Summary of Safety and Effectiveness

Submission in accordance with the requirements of 21 CFR Part 807.87(h).

Submitter	: Medis medical imaging systems bv
Address	: Schuttersveld 9
	: 2316 XG Leiden
	: The Netherlands
Contact Person	: B. Goedhart, PhD, VP Corporate R&D
Email	: bgoedhart@medis.nl
Telephone	: +31 71 522 3244
Fax	: +31 71 521 5617

Prepared	: January 5, 2015
Trade / Device Name	: MR-CT VVA
Common Name	: Radiological Image Processing Software
Regulatory Class	: II
Regulation Description	: Picture Archiving and Communications System
Regulation / Procode	: 21 CFR 892.2050 / LLZ

Predicate Devices

- The Cardiovascular Imaging Solutions Ltd.: **CMRtools™ (K073194)**
- The GE Healthcare: **CardiacVX™ (K121762)**

Device Description

MR-CT VVA (MR-CT Vessel and Ventricular Analysis) is image post-processing software for the viewing and quantification of MR and CT images of blood vessels, of the heart and MR images of the liver and cerebral spinal fluid. Semi-automatic contour detection forms the basis for the analyses. Its functionality is independent of the type of vendor acquisition equipment. The analysis results are available on screen and can be exported in various electronic formats.

MR-CT VVA has been developed as a standalone application to run on a Windows based operating system. The import of images and the export of analysis results are via CD / DVD, a PACS or network environment.

MR-CT VVA has a modular structure that consists of its previously cleared predicate devices: MRI-MASS, CT-MASS, MRI-FLOW, CMS-VIEW and MRA-CMS. MR-CT VVA comprises their respective functionalities for analyzing the blood vessels and the heart. In addition, MR-CT VVA includes new functionality for the 3D review of MR volumetric data.

Intended Use

MR-CT VVA is software intended to be used for the visualization and analysis of MR and CT images of the heart and blood vessels.

MR-CT VVA is intended to support the following visualization functionalities:

- cine loop and 2D review
- double oblique review
- 3D review by means of MIP and volume rendering
- 3D reformatting
- performing caliper measurements

MR-CT VVA is also intended to support the following analyses:

- cardiac function quantification
- MR velocity-encoded flow quantification
- anatomy and tissue segmentation
- signal intensity analysis for the myocardium and infarct sizing
- MR parametric maps (such as T1, T2, T2* relaxation)

MR-CT VVA is also intended to be used for:

- quantification of T2* results in MR images that can be used to characterize iron loading in the heart and the liver
- MR velocity-encoded flow quantification of cerebral spinal fluid

These analyses are based on contours that are either manually drawn by the clinician or trained medical technician who is operating the software, or automatically detected by the software and subsequently presented for review and manual editing. The results obtained are displayed on top of the images and provided in reports.

The analysis results obtained with MR-CT VVA are intended for use by cardiologists and radiologists to support clinical decisions concerning the heart and vessels.

Indications for Use

MR-CT VVA is indicated for use in clinical settings where more reproducible than manually derived quantified results are needed to support the visualization and analysis of MR and CT images of the heart and blood vessels for use on individual patients with cardiovascular disease. Further, MR-CT VVA allows the quantification of T2* in MR images of the heart and the liver. Finally, MR-CT VVA can be used for the quantification of cerebral spinal fluid in MR velocity-encoded flow images.

When the quantified results provided by MR-CT VVA are used in a clinical setting on MR and CT images of an individual patient, they can be used to support the clinical decision making for the diagnosis of the patient. In this case, the results are explicitly not to be regarded as the sole, irrefutable basis for clinical diagnosis, and they are only intended for use by the responsible clinicians.

Substantial Equivalence Information

Two devices have been selected as the predicate devices for MR-CT VVA: CMRtools™ and CardiacVX™.

CMRtools ("a software package for the visualization and analysis of cardiovascular MR images") and CardiacVX ("a post-processing analytical software application, which provides tools for review and reporting of cardiac MR datasets") have technological features and characteristics comparable to MR-CT VVA.

MR-CT VVA provides (see Intended Use description above) **visualization functionalities** for cine loop and 2D review and caliper measurements, which are also supported by CardiacVX ("Multi-phase sequences of images can be displayed in cine mode" and "Available tools include point, distance, area and volume measurement"). Further, MR-CT VVA provides visualization functionalities for 3D review and reformatting, which are also supported by CMRtools ("It allows high performance image manipulation, 3D visualization and advanced image processing").

MR-CT VVA provides (see Intended Use description above) **analysis functionalities** for cardiac function quantification, flow quantification, which are also supported by CardiacVX ("Semi-automatic tools are available for left ventricular contour detection, valve plane detection and vessel contour detection for flow quantification"). Further, MR-CT VVA provides analysis functionalities for tissue segmentation and MR parametric maps (including T2* for the liver), which are also supported by CMRtools ("cardiac assessment for left ventricular assessment and Thalassaemia tools for image quantification ... to view and analyze human cardiac and liver images").

Next to this, the following devices from Medis medical imaging system bv are predecessors of MR-CT VVA and can be used as reference devices: MRI-MASS (K994283), CT-MASS (K033774), MRI-FLOW (K994282), CMS-VIEW (K993761), and MRA-CMS (K040746).

Conclusions

MR-CT VVA has the same intended use as the predicate devices.

MR-CT VVA complies with international process standards (ISO 13485, ISO 14971 and IEC 62304).

Testing and validation have produced results consistent with design input requirements. MR-CT VVA is a software-only device for which there no applicable mandatory performance standards.

During the development, potential hazards were controlled by a risk management plan, including risk analysis, risk mitigation, verification and evaluation.

Medis concludes that MR-CT VVA is a safe and effective medical device, and is at least as safe and effective as its predicate devices. The use of MR-CT VVA does not change the intended use of MRI or CT scanners, nor does the use of this software result in any new potential hazards.